K 063561

7 510(k) Summary

JAN 19 2007

Submitter:	Moor Instruments Ltd
Address:	Millwey Axminster, Devon EX13 5HU, United Kingdom
Telephone:	(+44) 1297 35715
Fax:	(+44) 1297 35716
Contact:	Xiabing Huang
Contact title:	Technical Manager
E-mail:	xhuang@moor.co.uk
Date:	November 17, 2006
Model Name:	moorLDLS Laser Doppler Line Scanner
Model Number:	moorLDLS
Common Name:	Laser Doppler Imager
Classification Name:	Extravascular blood flow probe, DPT, 21 CFR 870.2120 Laser surgical instrument for use in general and plastic surgery and in dermatology, GEX, 21 CFR 878.4810
Regulatory Status:	Class II
Establishment Reg No:	8043564
Type of 510(k):	Traditional
Reason for submission:	New device
Predicate Device:	moorLDI2-IR Infrared Laser Doppler Imager 510(k) Number K032841

Moor Instruments Ltd Millwey Axminster Devon EX13 5HU UK
tel +44 (0)1297 35715 fax +44 (0)1297 35716
email sales@moor.co.uk website www.moor.co.uk
Company Registered in England No. 2209367 VAT Registration No. GB490667906

7.1 Description of the Device

The moorLDLS laser Doppler line scanner is a device for imaging blood flow in the microcirculation. It uses the established laser Doppler technique to quantify movement of blood cells beneath the skin surface. Unlike the predicate device moorLDI2-IR laser Doppler imager, which use a single low power infrared laser beam, the moorLDLS line scanner sweeps a line of laser light across the tissue to build up a colour coded image of blood flow rapidly.

7.2 Intended Use

The moorLDLS Laser Doppler Line Scanner is intended for blood flow measurements in the microcirculation.

7.3 Technological Characteristics

The operation and design of the moorLDLS line scanner and moorLDI2-IR laser Doppler image are very similar. They both have the same intended use. Both devices rely on the same physical principle, i.e. the laser Doppler principle, to measure the tissue blood perfusion.

The main difference between two devices is the scanning method. The moorLDI2-IR device scans a low power laser beam over the tissue surface in a raster pattern to produce a two dimensional colour coded blood perfusion image, while the moorLDLS line scanner uses a low power laser line to sweep across the tissue for rapid scanning.

7.4 Performance Data

In order to evaluate the performance of the moorLDLS laser Doppler line scanner, and determine its substantial equivalence to the predicate device moorLDI2-IR, a set of comparison tests has been carried out. These include flow model and image scan using both devices. The results suggest that moorLDLS line scanner has achieved the same performance as the predicate device moorLDI2-IR laser Doppler imager.

The moorLDLS line scanner has been designed and tested for compliance with the standards for electrical safety, laser radiation safety, electromagnetic compatibility and programmable medical device.

7.5 Conclusions

From the description of the technological characteristics and the performance data, it can be concluded that the moorLDLS laser Doppler line scanner is substantial equivalence to the predicate device moorLDI2-IR laser Doppler imager in terms of effectiveness and safety.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Moor Instruments Ltd
% Xiabing Huang
Technical Manager
Millwey
Axminster, Devon
EX13 5HU United Kingdom

JAN 19 2007

Re: K063561
Trade/Device Name: moorLDLS Laser Doppler Line Scanner
Regulation Number: 21 CFR 870.2120
Regulation Name: Extravascular blood flow probe
Regulatory Class: Class II
Product Code: DPT
Dated: November 17, 2006
Received: November 27, 2006

Dear Xiabing Huang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115 Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

5 Indications for Use Statement

510(k) Number: K 063561

Device name: moorLDLS Laser Doppler Line Scanner

Indications for use:

The moorLDLS Laser Doppler Line Scanner is intended for blood flow measurements in the microcirculation.

Prescription Use: Yes
(Part 21 CFR 801 SubpartD)

AND/OR

Over-The-Counter Use: No
(21 CFR 807 Subpart C)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K063561